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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,738	05/09/2001	Thomas R. Coolidge	P03660US5	4849
27141	7590	11/03/2004	EXAMINER	
MCKEE, VOORHEES & SEASE, P.L.C. ATTN: BIONEBRASKA 801 GRAND AVENUE, SUITE 3200 DES MOINES, IA 50309-2721			LIU, SAMUEL W	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/851,738

Applicant(s)

COOLIDGE ET AL.

Examiner

Samuel W Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-22 and 24-42 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14-21, 24-31, 34, 41 and 42 is/are allowed.
- 6) ☒ Claim(s) 22, 32, 33 and 35-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of the claims

Claims 14-22 and 24-42 are pending.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7 September 2004 has been entered. Also, Applicant requests petition for extension of time of one-month has been entered.

Applicant's response filed 7 September 2004 which amends claims 14, 17, 20, 24 and 32-33, and adds claims 34-42 has been entered. Thus, claims 14-22 and 24-42 are pending. The following Office Action is applicable to the pending claims 14-22 and 24-42.

Claim Rejections - 35 USC § 112, the second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 22, 32-34, 37 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 22 recites the limitation “a medical procedure”. There is insufficient antecedent basis for this limitation in claim 14 from which claim 22 depends. See also claim 31. The dependent claims are also rejected.

Claims 32-33 and 37 are indefinite because the claim recitation “administering an anti-inflammatory” appears to be incomplete. Suggest addition of “agent” or drug” after the recitation.

Provisional Rejection - Obviousness Type Double Patenting

Claims 35-40 of this application conflict with Claims 1, 7, 11 and 25 of Application No. 09953021. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130 (b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 35-39 are provisionally rejected under the judicially created doctrine of double patenting over claims 1, 7, 11 and 25 of Application No. 09953021. This is a provisional double patenting rejection because the conflicting claims have not in fact been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows:

Claim 1 of 09953021 discloses a method of preventing or ameliorating an organ tissue injury by reperfusion after ischemia comprising administering to a subject a GLP-1 receptor binning compound (including GLP-1 agonist), which is the common subject matter (though different in the scope) of the instant claim 35.

09851738 describes that ischemia is caused by heart surgeries, i.e., cardiac surgical procedure (see the 2nd to the last paragraph, page 1). Thus, the claim 1 disclosure is also applied to the instant claim 36.

Claim 25 of 09953021 sets forth that the claim 1 method comprises the step of reducing inflammatory response, which is a common subject matter of the instant claim 37.

Claim 7 of 09953021 sets forth that in the claim 1 method, administering a free radical scavenger, which is an obvious variation of the instant claim 38.

Claim 11 of 09953021 is identical to the instant claim 39.

In the "Detailed Description of the Invention", 09851738 sets forth reperfusion therapy (see page 8). Thus, claim 1 of 09953021 is an obvious variation of the instant claim 40.

Thus, the instant application and 09953021 claims are obvious variation.

Claim Rejection –Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Claims 35-36 and 38-40 are rejected under the judicially created doctrine of the obviousness-type double patenting of claims 1, 7 and 11 of US Pat. No.6284725. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claim 1 of 6284725 discloses a method of ameliorating an organ tissue injury by reperfusion after ischemia comprising administering to a subject a compound that binds to a GLP-1 receptor (including GLP-1 agonist), which is the common subject matter (though different in the scope) of the instant claim 35.

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6284725 describes that ischemia is caused by heart surgeries, i.e., cardiac surgical procedure (see column 1, lines 33). Thus, the claim 35 disclosure is also applied to the instant claim 36.

Claim 7 of 6284725 sets forth that in the claim 1 method, administering a free radical scavenger, which is an obvious variation of the instant claim 38.

Claim 11 of 6284725 is identical to the instant claim 39.

In the "Detailed Description of the Invention", 6284725 sets forth reperfusion therapy (see column 5, lines 23-26). Thus, claim 1 of 6284725 is an obvious variation of the instant claim 40.

Thus, claims 1, 7 and 11 of 6284725 claims 35-36 and 38-40 of the current application are not patentably distinct from each other.

Conclusion

Claims 22, 32-33 and 35-40 are not allowed. Claims 14-21, 24-31, 34 and 41-42 are allowable over prior art in record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-

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9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

SWL

Samuel Wei Liu, Ph.D.

October 18, 2004

Karen Cochrane Carlson Ph.D.

KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER